PATENT DBC: M190.137.101

Medtronic: P-9924.01

## What is claimed is:

1. An annuloplasty band for repair of an atrio-ventricular valve forming a valve annulus, the band comprising:

a sheath;

a generally arcuate stiffening element disposed within the sheath, the stiffening element extending from a first end to a second end, wherein each of the first and second ends includes an eyelet adapted to receive a suture for securing the annuloplasty band to the valve annulus.

2. The annuloplasty band of claim 1, wherein the valve is a mitral valve having an antero-lateral trigone, a posterior leaflet, and a postero-medial trigone, and further wherein the eyelets are adapted to secure the annuloplasty band to the intero-lateral trigone and the postero-medial trigone, respectively, via sutures.

3. The annuloplasty band of claim 1, wherein the valve is a tricuspid valve having an anterior leaflet, a posterior leaflet and a septal leaflet, each of the leaflets defined by a base relative to the valve annulus, and further wherein the eyelets are adapted to secure the annuloplasty band to the base of the septal leaflet and the based of the anterior leaflet, respectively, via sutures.

4. The annuloplasty band of claim 1, wherein the stiffening element includes a wire having opposite ends bent back onto itself to form the eyelets.

5. The annuloplasty band of claim 4, wherein the wire is overmolded with an elastomeric material.

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6. The annuloplasty band of claim 5, wherein the elastomeric material includes a material selected from the group consisting of biocompatible thermal plastic elastomer and silicone.

- 7. The annuloplasty band of claim 4, wherein the wire is configured to define a compound curve including an intermediate portion having a first radius of curvature and opposite end portions each having a second radius of curvature, wherein the first radius of curvature is greater than the second radius of curvature.
- 8. The annuloplasty band of claim 7, wherein each of the end portions includes: a transition segment extending outwardly from the intermediate portion, the transition segment having the second radius of curvature;

an end segment extending from the transition segment, the end segment having a third radius of curvature;

wherein the second radius of curvature is greater than the third radius of curvature.

- 9. The annuloplasty band of claim 1, wherein the stiffening element includes a molded polymeric element.
- 10. The annuloplasty band of claim 1, wherein the sheath is marked to indicate eyelet position.
- 11. The annuloplasty band of claim 10, wherein the sheath is marked to indicate eyelet placement by a suture having a color different from a color of the sheath.
- 12. The annuloplasty band of claim 1, wherein the stiffening element is radio-opaque.

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13. The annuloplasty band of claim 1, wherein the sheath is formed of a fabric material.

- 14. The annuloplasty band of claim 1, wherein the sheath is formed of biological tissue.
- 15. The annuloplasty band of claim 1, wherein the band has a thickness no greater than approximately 3 mm.
- 16. The annuloplasty band of claim 1, wherein the stiffening element is generally arcuate in an X-Y plane and generally saddle-shaped in a Z-plane.
- 17. A method of implanting an annuloplasty band for repairing an atrioventricular valve defining a valve annulus, the method comprising:

providing an annuloplasty band including a sheath and a generally arcuate stiffening element disposed within the sheath, the stiffening element extending from a first end to a second end, each end forming an eyelet adapted to receive a suture;

positioning the annuloplasty band along the valve annulus; and suturing the respective eyelets to tissue of the valve annulus.

- 18. The method of claim 17, wherein the atrio-ventricular valve is a mitral valve defining an antero-lateral trigone and a postero-medial trigone, and further wherein suturing the eyelets includes suturing the eyelet of the first end to the antero-lateral trigone and suturing the eyelet of the second end to the postero-medial trigone.
- 19. The method of claim 17, wherein the atrio-ventricular valve is a tricuspid valve defining an anterior leaflet and a septal leaflet, each of the leaflets forming a base relative to the valve annulus, and further wherein suturing the eyelets includes suturing the eyelet of the first end to the base of the anterior leaflet adjacent the

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valve annulus and suturing the eyelet of the second end to the base of the septal leaflet adjacent the valve annulus.

- 20. The method of claim 17, wherein providing an annuloplasty band includes forming markings on the sheath indicative of locations of the eyelets, and further wherein suturing the eyelets include passing sutures through the respective markings.
- 21. A combination annuloplasty band and holder for use by a surgeon in conjunction with annuloplasty surgery performed on a patient's heart valve defining a valve annulus, comprising:

an annuloplasty band comprising a sheath and a generally arcuate stiffening element disposed within the sheath, the stiffening element extending from a first end to a second end, wherein each of the first and second ends forms an eyelet adapted to receive a suture for securing the annuloplasty band to the valve annulus; and

a holder selectively maintaining the annuloplasty band, the holder including a band-retaining plate forming a perimeter defining a curvature corresponding generally with a curvature of the annuloplasty band, the perimeter further forming cut-out areas adapted to provide clearance about the eyelets upon mounting of the annuloplasty band to the band-retaining plate.

- 22. The combination of claim 21, wherein:
  the stiffening element comprises a wire having opposite ends bent back onto
  itself to form the eyelets; and
  the wire is overmolded with an elastomeric material.
- 23. The combination of claim 21, wherein the sheath is marked to indicate eyelet placement.

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24. The combination of claim 23, wherein the sheath is marked to indicate eyelet placement by a suture having a color contrasting with a color of the sheath.

- 25. The combination of claim 21, wherein the annuloplasty band and the band-retaining plate are adapted for repairing a mitral valve.
- 26. The combination of claim 21, wherein the annuloplasty band and the band-retaining plate are adapted for repairing a tricuspid valve.
- 27. A holder for an annuloplasty band including a band-retaining plate forming a perimeter defining:

an arcuate segment

opposing cut-out regions extending from opposite sides of the arcuate segment, respectively; and

a trailing segment extending between the opposing cut-out regions opposite the arcuate segment;

wherein the opposing cut-out regions each define a transition from the arcuate segment to the trailing segment, the cut-out regions each having a first portion extending inwardly from the arcuate segment and a second portion extending outwardly from the first portion to the trailing segment.

- 28. The holder of claim 27, wherein the arcuate segment defines an arc length corresponding generally with an arc length of an annuloplasty band, and wherein the cut-out regions are each adapted to provide access to an eyelet portion of the annuloplasty band when mounted to the band-retaining plate.
- 29. The holder of claim 27, wherein the trailing segment tapers inwardly between the opposing cut-out regions.

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30. An annuloplasty band for repair of an atrio-ventricular valve of a patient's heart, the band comprising:

a sheath; and

a generally arcuate stiffening element disposed within the sheath, the stiffening element having rounded ends;

wherein the band has a thickness no greater than about 3 mm.

- 31. The annuloplasty band of claim 30, wherein the band has a thickness no greater than about 2.7 mm.
- 32. The annuloplasty band of claim 30, wherein the band has a thickness no greater than about 2.5 mm.
- 33. The annuloplasty band of claim 30, wherein stiffening element forms eyelets at the ends thereof.
- 34. A sizer device for use in evaluating a size of an atrio-ventricular valve annulus as part of a valve repair procedure, the sizer device including a sizer forming a perimeter defining:
  - a leading segment shaped in accordance with a portion of a shape of a natural atrio-ventricular valve annulus;

a trailing segment opposite the leading segment, and

- opposing cut-out segments located at opposite sides of the leading segment, respectively, wherein the opposing cut-out segments are adapted to facilitate viewing of portions of the valve annulus upon placement of the sizer into close proximity to the valve annulus.
- 35. The sizer device of claim 34, wherein the leading segment is shaped in accordance with a posterior portion of a mitral valve, and further wherein the

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opposing cut-out segments are adapted to facilitate viewing of the antero lateral trigone and the postero-medial trigone, respectively.

36. The sizer device of claim 34, wherein the sizer further includes indicia adapted to highlight a location of the opposing cut-out segments.